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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/798,603	03/10/2004	Brent Nistal	89000.3014NP	6165
20601	7590	01/19/2006	EXAMINER	
SPECKMAN LAW GROUP PLLC 1201 THIRD AVENUE, SUITE 330 SEATTLE, WA 98101			GILBERT, ANDREW M	
			ART UNIT	PAPER NUMBER
			3767	

DATE MAILED: 01/19/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

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<b>Office Action Summary</b>	<b>Application No.</b> 10/798,603	<b>Applicant(s)</b> NISTAL ET AL.	
	<b>Examiner</b> Andrew M. Gilbert	<b>Art Unit</b> 3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 9/2/2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 10 March 2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)               | Paper No(s)/Mail Date. _____  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>9/2/2005</u> .  | 6) <input type="checkbox"/> Other: _____                                    |

## **DETAILED ACTION**

### ***Information Disclosure Statement***

1. The information disclosure statement (IDS) submitted on 9/2/2005 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

### ***Drawings***

2. The drawings are objected to under 37 CFR 1.83(a) because they fail to clearly show the catheter tube, the adapter tube, the shrink wrap and shrink wrap extension in Figs 4A and 4B as described in the specification. Any structural detail that is essential for a proper understanding of the disclosed invention should be shown in the drawing. MPEP § 608.02(d). Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the

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examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

3. The drawings are objected to because lines are not uniformly thick, well defined, and clean. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

### ***Specification***

4. The use of the trademark "TEFLON" in claims 7, 14, 18 and in the specification on [0014, ln 4] and [0034, ln 2] and the trademark "CO-PILOT™" on [0007, ln 1] has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

***Claim Objections***

5. Claim 1 is objected to because of the following informalities: Claim 1 recites the limitation "the connector" in Ins 2, 3 and the limitation "the catheter" in Ins 8, 9. There is insufficient antecedent basis for this limitation in the claim. Appropriate correction is required.

***Claim Rejections - 35 USC § 102***

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1, 2, 6-9, 13-15, and 17-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Stevens (4798586). In reference to claims 1, 2, 6-9, 13-15, and 17-20, Stevens discloses an adapter (82) insertable into a connector (60), the adapter having a rigid tube (83) whose distal portion is insertable within the connector (Fig 6), a lumen sized to allow a catheter (64) to pass through it (Fig 7), a Teflon thermally shrinkable wrap (84; col 5, Ins 1-22) that extends from the distal end of the tube and forms an extension section that surrounds a portion of the catheter (Fig 7) and a portion of the shrinkable wrap covers the tube and is shrinkable to a first diameter being the diameter

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of the tube and the extension section is shrinkable to a diameter that is the diameter of the catheter (Fig 7; col 5, lns 1-22).

8. In reference to claims 15 and 17-20 Stevens additionally discloses a catheter system having an operating head (32) coupled to a distal end of the catheter system (Fig 2), a drive shaft (62) extending within the catheter system, a drive system (70) to rotate the drive shaft (col 4, lns 50-64), and a control system (71; Fig 11) to direct the rotation of the drive shaft.

***Claim Rejections - 35 USC § 103***

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Claims 3, 4, 10, 11, and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stevens in view of Imran et al (5779688). Stevens discloses the invention substantially as claimed except for the tube being securely clinched by a tightening segment being a Touhy Borst valve. Imran et al teaches that it is known to have a tightening segment being a Touhy Borst valve (52; col 4, lns 30-50) that securely clinches a tube (Fig 1) for the purpose of securely clinching and providing a fluid tight seal. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the connector as taught by Stevens with the Touhy Borst

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valve tightening segment as taught by Imran et al for the purpose of securely clinching and providing a fluid tight seal.

11. Claims 5 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stevens. Stevens discloses the invention substantially as claimed except for expressly disclosing the connector being a Y shaped adapter. At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to modify the T shaped adapter with a side port (94; Fig 8) because the Applicant has not disclosed that a Y shaped adapter provides an advantage, is used for a particular purpose, or solves a stated problem. Furthermore, one of ordinary skill in the art would have expected the Applicants invention to perform equally well with the T shaped adapter of Stevens because the T shaped adapter performs the same purpose of having a side branch (92) to allow radio-opaque dye to be injected into or from the catheter (col 5, ln 32-42). Therefore, it would have been an obvious matter of design choice to modify Stevens to obtain the invention as specified in claims 5 and 12.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Andrew M. Gilbert whose telephone number is (571) 272-7216. The examiner can normally be reached on 8:30 am to 5:00 pm Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571)272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Andrew Gilbert

